

## REMARKS

1. Claims 16-28 have been cancelled; Claims 30-44 are new.
2. **Response to Examiner's Rejections under 35 U.S.C. 102(b):**

In the March 9, 2003 Office Action, the Examiner rejected Applicant's claims 1-5, 7, 9-13, 15-18, 20, 22-26, and 28 under 35 U.S.C. 102(b) as being anticipated by U.S. Pat No. 2,671,545 to Hall ("Hall"). MPEP 706.02 states that "for anticipation under 35 U.S.C. 102, the reference must teach *every aspect* of the claimed invention either explicitly or impliedly." Applicant submits to the Examiner that Hall fails to teach, either explicitly or impliedly, *every aspect* of Applicant's Claim 1. Applicant's Claim 1 includes the limitation "wherein said waist chain is positioned tightly around the waist of a person such that as said person's weight increases, said waist chain becomes increasingly tight." The foregoing language further limits Applicant's claimed invention to a waist chain *positioned on the waist of a person*. This limitation is neither explicitly nor impliedly disclosed in Hall. The Examiner makes the conclusion in the Office Action that "as to the preamble and claim 28, the intended use of the claimed chain is given little if any patentable weight in article claims; the claimed structure is met by Hall." Applicant suggests to the Examiner that the locational limitation of Claim 1 is not part of the preamble, but instead is an additional structural limitation. Further, even if the location of Applicant's waist chain were considered part of the preamble as suggested by the Examiner, MPEP 2111.02 states that "any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation." In light of the foregoing points, Applicant requests that Examiner provide Applicant with evidence supporting Examiner's

conclusion that the location of the waist chain should not be considered a claim limitation.

Even if the Examiner does not recognize the waist positioning location of Claim 1, new Claim 30 recites a “system” comprising a person and a waist chain. Claim 30 makes it even clearer that the positioning of the waist chain around the waist of a person is not a mere “intended use” of the waist chain, but instead is an actual limitation of the claimed system. Hall clearly does not anticipate new Claim 30.

3. **Response to Examiner’s Rejections under 35 U.S.C. 103(a) as being unpatentable over Hall:**

The Examiner rejected Claims 6, 8, 14 19, 21, and 27 under 35 U.S.C. 103(a) as being unpatentable over Hall stating that “Hall teaches the claimed invention excepting 1) the making of the links from stainless steel, 2) the making of the end link removably attachable, and 3) making the end connection permanently connectable to at least one of the ends of the chain.” The Examiner’s rejection under 35 U.S.C. 103(a) is inappropriate because Examiner fails to acknowledge the limitation contained in Applicant’s Claim 1 which limits the claimed invention to being “positioned tightly around the waist of a person.” 35 U.S.C. 103(a) requires that “the subject matter *as a whole* would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” Because Hall contains absolutely no suggestion of the limitation “positioned tightly around the waist of a person,” an obviousness rejection based on Hall alone is clearly improper.

4. **Response to Examiner’s Rejection of Claim 29 under 35 U.S.C. 103(a) as being unpatentable over the articles to “Management of Obesity. Another View,” J.S. Garrow**

**(1992) or “Intermittent Protein-Sparing Fasting With Abdominal Belting,” Simpson et al. (1986) when taken in view of Hall:**

A. No Prima Facie Case: The applicant respectfully submits that Examiner’s rejection of Claim 29 is contrary to the MPEP and therefore requests reconsideration of the rejection. The Examiner has not established a *prima facie* case of obviousness as required under MPEP §706.02(j). The Examiner found that the two above referenced articles taught “belting or using a cord around the waist of a wearer to prevent said wearer from over eating and gaining weight” and therefore concluded that “belting or cording is an old idea.” The Examiner then makes the unsupported statement that to have used other types of cords or belts to achieve the same result would have been obvious to one of ordinary skill in the art” and further concludes that “to have provided a chain or other structure like unto it, especially that of a ball chain which is easily adjustable and easy to wear, would have been such an obvious choice of belting expedients rendering no new or unobvious result to the process.” As provided for in MPEP §706.02(j), to establish a *prima facie* obviousness rejection, there must be a suggestion for the proposed combination either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. However, neither case applies in the Examiner’s rejection of claim 29.

First, Applicant submits there is absolutely nothing contained in neither the two articles that have been cited by the Examiner nor the Hall patent that would suggest combining the references. The two articles only discuss “nylon cords” and “nylon monofilaments” used for purposes of abdominal belting. Likewise, the invention disclosed in the Hall patent is

characterized therein simply as “an ornamental bead chain.” There is absolutely no mention in Hall of any intended function or use of the chain disclosed therein, and certainly no disclosure regarding positioning chains on the waist or body of a person. Applicant respectfully requests that the Examiner provide line and column numbers from any of the foregoing prior art references that suggests combining those references. Based upon Applicant’s review of the references, Applicant suspects that no such column or line numbers will be found.

Second, the Examiner has provided no support that there existed in the knowledge generally available to one of ordinary skill in the art at the time of Applicant’s invention, a suggestion to combine the teachings of Hall with the teachings of the two articles cited by the Examiner. In Office Action, the Examiner makes the unsupported and conclusory statement that “to have provided a chain or other structure like unto it, especially that of a ball chain which is easily adjustable and easy to wear, would have been such an obvious choice of belting expedients rendering no new or unobvious result to the process.” The Examiner has provided no objective evidence that supports the conclusion that combining beaded chains with waist cords was generally available to one of ordinary skill in the art at the time of Applicant’s invention. Such a casual and conclusory statement by the Examiner is not evidence of the level of knowledge generally available. Chains like the one disclosed in Hall would not intuitively be used for the treatment of obesity. Such prior art chains are commonly associated as pull switches of electronic lamp sockets as suggested in U.S. Pat No. 1,103,760 to Goodridge or chandelier chains or watch chains as suggested in U.S. Pat. No. 61,777 to Wallace, not chains to be worn around the waist of a person. Because the Examiner cannot find evidence that knowledge was

available at the time of Applicant's invention that would suggest combining beaded chains with waist cords, it is apparent that the Examiner is using Applicant's own disclosure to find a suggestion to combine. Such hindsight in combining references is prohibited by the MPEP.

Not only has the Examiner failed to show that there is a suggestion from the knowledge generally available to persons of ordinary skill in the art at the time of Applicant's invention to combine the teachings of Hall with the teachings of the two articles that were cited by Examiner, but the Declarations of Drs. Greenway and Fujioka, both of which are attached to this response, provide positive evidence that such knowledge did not exist. As discussed in more detail below, Dr. Greenway points out in his declaration that the nylon cords and monofilaments taught in the articles cited by the Examiner were plagued with problems that ultimately led to their disuse. The nylon cords and monofilaments were notorious for pinching the skin, holding bacteria that caused skin infections, being easy to cut and remove by patients and hard to clean. Dr. Fujioka echoed many of the foregoing flaws in his declaration, stating that nylon cords and monofilaments "cut into the skin of patients causing severe discomfort" and further stating that "the ease of removing the nylon cords and nylon monofilaments contributed to the disuse of prior abdominal belting methods." Further, Dr. Greenway reported objective results in his declaration of a study involving the comparison of the claimed waist chain invention with the prior art nylon cord and monofilament, which study showed that the waist chain did not possess the flaws of the prior art, and as a result, outperformed the prior art. Please see Dr. Greenway's Declaration for a more detailed accounting of the experiment performed and the results of that experiment. The declarations of Drs. Greenway and Fujioka clearly establish that there were flaws in the prior art

that led to its disuse, and further provide objective evidence that the claimed invention eliminates those flaws. Given the fact that the waist chain clearly outperforms the prior art, if the knowledge generally available to persons of ordinary skill was to use the Hall chain with the prior art nylon cords, then such a combination should have been disclosed in the two articles cited by the Examiner. Certainly chains such as seen in the Hall patent were publicly known at the time nylon cords fell into disuse. The reason such combination was not made at the time those experiments were conducted, and the reason that no such combination has since been made is because a suggestion to combine the teachings of Hall with the prior art disclosed in the articles was not within the knowledge generally available to persons of ordinary skill in the art at the time of Applicant's invention.

The Examiner has further failed to make a prima facie case under 35 U.S.C. 103(a) by citing prior art references that are non-analogous art under MPEP §2141.01(a). Examiner's reliance on Hall is improper because the beaded chain disclosed in Hall is *not* an analogous prior art to Applicant's invention. MPEP 904.01(c) provides that a determination of analogous art "depends upon the necessary essential function or utility of the subject matter covered by the claims." In addition MPEP 2141.01(a) provides that "in order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the invention is concerned." First, Applicant's field of endeavor pertains specifically to the treatment of obesity and is limited by the claims to a chain positioned around the waist of a person. The field of endeavor disclosed in Hall has absolutely no relevance whatsoever to the

field of Applicant's endeavor, namely the treatment of obesity. Instead, the chain in Hall was designed to overcome the difficulties associated with bead chains having alternating circular and elongated beads. Second, Hall has no pertinence to the particular problem with which the present invention is concerned. Hall described his problem as being when severing a chain consisting of alternating circular and elongated beads, an elongated bead would have to be removed from an end in order for that end to fit within a usual snap connector. The chain in Hall solved the problem of the prior art by placing two circular beads between each elongated bead. As a result, the chain of Hall could be severed between two adjacent circular beads and each severed end would have a circular bead for connection to a snap connector. Such a design eliminated the need for removing an elongated bead. As obvious from the above discussion, Hall has absolutely nothing to do with the problems with which Applicant's invention is concerned. Whereas Applicant's invention attempts to solve problems associated with the use of waist cords for treating obesity such as pinching the skin, comfort in fit around the waist, ability to be cut and removed and antibacterial properties, Hall addresses the problem of wasted chain links. The problems addressed by both inventions have no relevance or commonality whatsoever. As a result, Hall must not be considered as analogous art.

B. Evidence of Secondary Considerations: The fact that Examiner's suggested combination of the teachings of Hall with the teachings of the two articles was not known at the time of Applicant's invention is further evidenced by the following: i) Applicant's claimed invention has documented unexpected results in accordance with MPEP §716.02 and ii) there exists a long-felt need for Applicant's waist chain in accordance with MPEP §716.04.

i. MPEP 716.01(a) states that affidavits or declarations containing evidence of criticality or unexpected results must be considered by the examiner in determining the issue of obviousness of claims for patentability under 35 U.S.C. 103. As provided in MPEP 716.02(b), evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims. In order to show unexpected results, MPEP 716.02(e) states that “an affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a *prima facie* case of obviousness.” Applicant refers the Examiner to the Declaration of Dr. Frank L. Greenway, a copy of which is attached to this response. Dr. Greenway’s educational and professional experience qualifies him as an expert in the area of obesity treatment. In the declaration, Dr. Greenway reports factual findings from an experiment comparing the properties and performance of Applicant’s beaded chain with the nylon cord and nylon monofilament disclosed in the two articles cited by the Examiner. As part of the experiment reported by Dr. Greenway, six women wore each of the three designs (i.e. the beaded waist chain of Applicant’s claimed invention, the nylon cord and the nylon monofilament) from 3 to 7 days. Each of the women completed a question in the form of visual analog scales after wearing each design. The results from the questions posed to the patients were unexpected given the reported failures and subsequent disuse of the nylon cords and monofilaments (see below discussion regarding long-felt need for a further explanation on the failures and disuse of the prior art nylon waist cords). Please refer to the attached Declaration for a detailed reporting of the experiment results. To summarize those results, the beaded chain was easier to keep clean,



more comfortable, less irritating to the skin, pinched the skin less and was felt by the subjects to potentially be more helpful in aiding the subjects to loose weight. The foregoing unexpected results are attributable to properties possessed by Applicant's claimed invention which are not contained by the prior art (e.g. nonporous links). MPEP 716.02(a) provides that the presence of a property not possessed by the prior art is evidence of nonobviousness. Dr. Greenway reaches the conclusion in his Declaration that the results support the contention that the beaded chain overcomes the design failures that caused the prior designs to fall into disuse. As stated by Dr. Greenway, "the beaded chain has significant advantages that were unanticipated by its unsuccessful predecessors."

The properties of Applicant's claimed invention were found by Dr. Ken Fujioka, an expert in the area of obesity treatment, to possess advantages not possessed by the prior art. A copy of Dr. Fujioka's Declaration is attached to this response. In the Declaration, Dr. Fujioka states disuse of prior art waist cords "was a direct result of inherent properties of then-used nylon cords and nylon monofilament that resulted in unmanageable discomfort to the patients as well as posed potential sanitary risks." He sites numerous properties of Applicant's invention that provide significant advantages over the prior art. For example, Dr. Fujioka notes that use of a nonporous material such as the beads of Applicant's beaded waist chain, is essential to any device intended to be worn in contact with the skin for the length of time required for abdominal belting. Dr. Fujioka explains that non-porous material will have a huge advantage over a nylon cord due to its inert nature. Dr. Fujioka further declares that the beaded chain of Applicant's claimed invention is more difficult to cut and remove from a patient than nylon cords. He notes

that “impulsivity can be a real problem in obesity, and having the patient taking the extra time to obtain a pair of wire cutters will help keep the string of beads on longer.” Dr. Fujioka notes that the problem with nylon cords was that “when discomfort overcame the willpower of the patient, the patient could simply cut the nylon cord or monofilament with a pair of scissors.” He then states that “the data appears to be quite clear that once the belt comes off the weight can return.”

ii. Applicant submits that Examiner’s claim of obviousness is overcome by the fact that Applicant’s claimed invention satisfies a long-felt need in the art. MPEP 716.04 provides that establishing a long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depend on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. The articles cited by the Examiner are clear evidence that treatment of obesity using abdominal belting methods were recognized by those of ordinary skill in the art. Applicant now refers the Examiner to the Declaration of Dr. Ken Fujioka. In the Declaration, Dr. Fujioka declared that “despite the disuse of abdominal belting, there continues to be a great need for diverse methods to control obesity.”

Second, the long-felt need must not have been satisfied by another before the invention by the applicant. In his Declaration, Dr. Fujioka declared that the articles that have been cited by the Examiner indicate that abdominal belting, at the time the studies in those articles were conducted and when properly worn by patients, had positive results. He further declared that “despite those positive results, abdominal belting fell into disuse.” In 10 years of Dr. Fujioka’s

professional experience, he has “neither personally seen nor heard of any patient using abdominal belting as a means for maintaining or losing weight,” and to his knowledge, “using a restrictive method such as abdominal belting is not presently used as a means for maintaining or losing weight anywhere nor has it been used for many years.”

Referring now to the Declaration of Dr. Frank L. Greenway, Dr. Greenway declared that the reason that abdominal belting “fell into clinical disuse during the last 10-15 years was due to design flaws.” Dr. Greenway noted the following flaws with the nylon cords and monofilaments: the nylon cord absorbs moisture with bathing and sweating and due to its porous nature, is a source of bacterial contamination, makes clothing wet, creates an undesirable odor, causes the cord to stick to the skin, causes skin irritation and engenders a sanitation problem; neither the nylon cord nor the monofilament can easily move to conform to the body contours as the person changes position, especially if it is damp from sweat or bathing; the monofilament, by encircling the waist in three revolutions, can pinch the skin and cut into the skin surface; the nylon cord and monofilament can be cut off with a standard pair of scissors or a pocketknife; the nylon cord and monofilament can fatigue, wear and break over time, especially when a person strains during bowel movements; and the nylon cord and monofilament are not attractive when worn with a bathing suit or other clothing that allows the cord or fishing line to be seen. Dr. Greenway further declared that “I believe this disuse was a direct result of inherent properties of then-used nylon cords and nylon monofilament that resulted in unmanageable discomfort to the patients as well as posed potential sanitary risks.” The foregoing objective evidence presented in the Declarations of Dr. Greenway and Dr. Fujioka clearly evidence a long-felt need for an

improved waist chain in treating obesity.

Third, the invention must in fact satisfy the long-felt need. As mentioned in connection with above discussion on unexpected results, the comparative studies of Dr. Greenway resulted in the following conclusions: Applicant's chain was more attractive, easier to keep clean, more comfortable, less irritating to the skin, pinched the skin less and was felt by the subjects to potentially be more helpful in aiding the subjects to loose weight. The foregoing results evidence that Applicant's claimed invention satisfies the long-felt need of a waist chain that is effective in the treatment of obesity. In the expert opinion of Dr. Fujioka, "had beaded waist chains been used in lieu of nylon cords or monofilaments, it is my opinion that abdominal belting probably would not have fallen into disuse."

Applicant respectfully requests that Examiner take into consideration the above arguments and submits that the above new and amended claims are now in condition for allowance and respectfully requests allowance of the same.

Respectfully Submitted:

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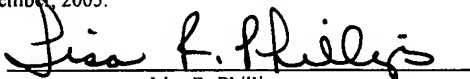
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I hereby certify that this correspondence is being deposited with the United States Postal Service in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 9th day of September, 2005.

  
Lisa R. Phillips